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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,619	07/03/2003	Douglas J. Allen	X-11666C	4376
25885	7590	04/02/2007	EXAMINER	
ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/02/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/02/2007.

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patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/613,619	ALLEN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Blessing M. Fubara	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 December 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-7,10-17,21-24 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-7,10-17,21-24 and 34 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Examiner acknowledges receipt of request for continued examination and remarks filed 12/12/2006. Claims 1, 3-7, 10-17, 21-24 and 34 are pending.

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 12/12/2006 has been entered.

### **Status of the claims**

The claims filed December 20, 2004 are pending. In the amendment filed 12/20/2004, claims 2, 8, 9, 18-20 and 25-33 are cancelled. Claims 1, 4, 5, 17 and 34 are amended. Claims 1, 3-7, 10-17, 21-24 and 34 are pending. Attorney Nelson L. Lentz authorized the cancellation of claim 24 in the interview of 9/29/06. However, since the allowed claims have not been issued and since applicant requested reconsideration of the claims, applicant may cancel at least claim 24 in response to this action. Thus, claims 1, 3-7, 10-17, 21-24 and 34 are considered in this Office Action.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1, 4-7, 10-17 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Sustained release has a release date of up to 30 days and greater than 7 days, which includes greater than 30 days is not supported (see paragraph [0058] of the published application).

NB: Attorney Nelson L. Lentz authorized amendment of claim 1 with respect to 7 days and 30 days in the interview of 9/29/06. See below for action necessary to overcome this rejection, which is commensurate with the interview of 9/29/06.

5. Claims 1, 4-7, 10-17 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

Claim 1 requires “oleaginous carrier” and “cholesterol microsphere carrier.” Dependent claim 4 limits the carrier to non-ionic copolymers of propylene oxide and ethylene oxide, cellulose gums, polysaccharide gums, vegetable oils, refined fractionated oils, sucrose diacetate hexaisobutyrate, lecithin and polyvinyl pyrrolidone. There is no description stating which carrier is “oleaginous” and which carrier is “cholesterol microsphere carrier.”

6. Claims 4-7, 10-17 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires “oleaginous carrier” and “cholesterol microsphere carrier.” Dependent claim 4 limits the carrier to non-ionic copolymers of propylene oxide and ethylene oxide, cellulose gums, polysaccharide gums, vegetable oils, refined fractionated oils, sucrose diacetate hexaisobutyrate, lecithin and polyvinyl pyrrolidone.

It is not clear how the carriers in claims 4 and 5 limit “oleaginous carrier” or “cholesterol microsphere carrier”. Oleaginous is understood to mean oily (see page 866 of the second college edition of The American Heritage Dictionary, 1976). Propylene oxide-ethylene oxide copolymer (PLURONIC), cellulosic gum, polysaccharide gum, chitosan and sucrose diacetate hexaisobutyrate are not within the scope of oils or “oleaginous” as claimed. Claims 4, 5 and 17 define “oleaginous carrier or cholesterol microsphere carrier” as being the various polymers recited in these claims, which is repugnant to the definition of oleaginous or cholesterol.

Furthermore, for claim 17, propylene oxide-ethylene oxide copolymer (PLURONIC), cellulosic gum and polysaccharide gum do not appear to be oleaginous or oils.

Claim 6 depends on canceled claim 2.

The particle size recited in claim 24 is outside the particle size recited in claim 23.

A “burst release of less than 15% of the active ingredient” is unclear. Is 15% of the active ingredient released in the burst release cycle or does the burst release put forth less than 15% of the active ingredient? Explanation/correction is respectfully requested.

To overcome the above rejection, the following below is suggested commensurate with the interview of 9/29/06:

- a) in claim 1, line 5, after “and” add ---up to 30 days---
- b) in claim 4, line 3, after “cellulosic” delete the comma
- c) in claim 6, line 1, after “claim” change 2 to 1
- d) delete/cancel claim 24

New suggestion from the above a-d

- e) Cancel claims 4, 5 and 17 or remove from claims 4, 6 and 17 materials that are not oils and specific what the carrier is in claims 4 and 5, that is, “oleaginous carrier” or “cholesterol microsphere carrier.”

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 1, 4-7, 10-17, 21-24 and 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5 and 7 of U.S. Patent No. 6,169,084 in view of Baxter et al. (US H0,000,672 H).

Issued method claim 7 administers olanzapine pamoate monohydrate of issued claims 3 and 5 for treating psychosis, acute mania or mild anxiety. In general, drugs, such as olanzapine pamoate monohydrate, are administered with one or more carriers. For example, Baxter in US H0,000,672 H at column 2, lines 62, 66 and 67 discloses the use of non-aqueous oleaginous liquid such as mineral oil, vegetable oil and hydrogenated fat as carrier for antifungal agent. Therefore, it is *prima facie* obvious to administer olanzapine pamoate monohydrate according to claims 7, 1 and 3-5 using carrier materials such as oleaginous liquid..

#### *Response to Arguments*

The examiner has taken note of applicant's clarification of the scope of the claims as it relates to the reasons for allowance. The clarification will be revisited once the claims are placed in condition for allowance by overcoming the rejections in this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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